K002833

SEP 2 8 2000

Standard Imaging

September 1, 2000

Subject: 510(k) Summary of Safety and Effectiveness Information for the Standard Imaging PT 1000 Ion Chamber

Proprietary Name: Standard Imaging PT 1000 Ion Chamber

Common Name: Ion Chamber

Classification: Class II – 21CFR892.5700, 90JAQ or
Class I – 21CFR892.5650, 90IWJ
Class I – 21CFR892.1940, 90LHO

Panel: Radiology

Contact Person: Raymond Riddle, Vice President, Regulatory Affairs

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The Standard Imaging PT 1000 Ion Chamber is substantially equivalent to the Standard Imaging HDR 1000 Ion Chamber, which was cleared by FDA with 510(k) premarket notification K922554 and the Standard Imaging HDR 1000 Plus/ IVB 1000 Well Chambers, which were cleared by FDA with 510(k) premarket notification K001825

The Standard Imaging PT 1000 Ion Chamber is a pass-through well-type chamber. It is specifically designed for use with both the brachytherapy high-dose-rate (HDR) remote afterloading irradiators, low-dose-rate (LDR) brachytherapy sources and intravascular (IVB) brachytherapy sources, with the appropriate calibration. It is recommended that the chamber be calibrated every two years, as is standard practice for other ionization chambers. Initially, the calibration factor is given in the calibration report from an Accredited Dosimetry Calibration Laboratory (ADCL).

The measurement of brachytherapy sources requires an electrometer with a calibrated scale for measuring currents in the range from 10^{-8}A to 10^{-7}A. Alternatively, a calibrated charge scale may be used with timed runs. If integral charge techniques are used with the time determined by the HDR irradiator timer, the contribution from the source transit-time should be taken into account.

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The PT 1000 Ion Chamber has a vent hole to maintain the internal air at ambient atmospheric pressure. Thus, the readings obtained must be corrected for ambient temperature and pressure to the temperature and pressure of calibration (22° C and 760 mm Hg) at "normal" relative humidity (50% ± 25%non-condensing) in the usual accepted manner. The PT 1000 has available different inserts for HDR and LDR measurements.

The PT 1000 Ion Chamber has a conventional triax connector and cable to be connected to a suitable electrometer. A bias of 300 volts must be applied to the electrometer low-impedance connection relative to chassis ground. The voltage polarity effect is less than 0.1%. If desired, a second bias level of 150 volts can also be used to determine the ionic recombination loss at 300 V.

The Standard Imaging PT 1000 Ion Chamber was designed to comply with the limited applicable portions of the following voluntary standards:

1. IEC 601-1: 1988 - Medical Electrical Equipment
2. IEC 60731: 1997 – Medical Electrical Equipment – Dosimeters with ionization chambers used in radiotherapy.

The Standard Imaging PT 1000 Ion Chamber and the predicate Standard Imaging HDR 1000, HDR 1000 Plus and IVB 1000 Ion Chambers are substantially equivalent in design concepts, technologies, materials and intended uses. The Standard Imaging PT 1000 Ion Chamber has been validated through calibration testing conducted by the University of Wisconsin – Madison, Department of Medical Physics Accredited Dosimetry Calibration Laboratory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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SEP 2 8 2000

Raymond T. Riddle
Vice President, Regulatory Affairs
Standard Imaging
7601 Murphy Drive
Middleton, WI 53562-2532

Re: K002833
Standard Imaging PT 1000 Ion Chamber
Dated: September 1, 2000
Received: September 12, 2000
Regulatory class: II
21 CFR 892.1360/Procode: 90 KPT

Dear Mr. Riddle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002833

Device Name: Standard Imaging PT 1000 Ion Chamber

Indications For Use:

The Standard Imaging PT 1000 Ion Chamber is a pass through well-type chamber. It is specifically designed to measure the amount of radiation of high-dose-rate (HDR), low-dose-rate (LDR) and intravascular (IVB) brachytherapy sources, with the appropriate calibration.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seppman

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and
Neurological Devices

510(k) Number: K002833

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801.109) (Optional Format 1-2-96)